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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,236	07/06/1998	YOSHIHIDE MATOBA	PM255089/SCC	9423

7590 09/15/2003  
FITHCH, EVEN, TABIN & FLANNERY  
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Washington, DC 20006

EXAMINER

MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/101,236

Applicant(s)

MATOBA ET AL.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003 and 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-18 and 20-44 is/are pending in the application.
- 4a) Of the above claim(s) 3-18 and 21-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,20, and 37-44 is/are rejected.
- 7) ☒ Claim(s) 1 and 19 have been canceled. ~~is/are rejected.~~
- 8) ☒ Claim(s) 2-18 and 20-44 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

Art Unit: 1631

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed on 5/27/03 and requested for entry as per the RCE, filed 6/27/03, has been entered.

Applicants' arguments, filed 5/27/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **COMMENT ON NEWLY ADDED CLAIMS 43 AND 44**

It is noted that newly added claim 43 includes a citation of the optional practice of non-elected species B and C as summarized in the Office action, mailed 8/31/01, and non-elected in Paper No. 10, filed 9/28/01. Claim 44 depends from claim 43 and clearly cites the elected Specie A as elected in Paper No. 10, filed 9/28/01. Consistent with the specie election, claim 43 will therefore only be examined at this time to the extent of the elected Specie A which is deemed an embodiment in both claims 43 and 44.

### **NEW MATTER**

Claims 2, 20, and 37-44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1631

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the instant claims under examination reveals that the parameter "N" is cited as being the "residual amount" in independent claims 37, 42, and 43. This contrasts with parameter "N" being defined as "chemical mass" in the instant specification on page 2, line 3, as well as admitted as being "chemical mass" in REMARKS, filed 5/27/03, on page 18, line 17. Thus, the written basis for "N" being "residual amount" per se has not been found as filed and therefore is NEW MATTER. Claims dependent directly or indirectly from independent claims 37, 42, and 43 are also included hereinunder due to their dependence therefore resulting in such claims also containing the above described NEW MATTER.

Further consideration of the instant claims has revealed that claim 37 was not originally filed, but rather added by amendment. Within claim 37 the last three lines are directed to the "confirming" of a mass balance of a compound under changing a minute time unit. Consideration of the support pointed to by applicants in the amendment, filed 5/30/02, reveals that page 57 of the instant specification has been pointed to regarding support for newly added claims 37 and 42. Confirming is reasonably interpreted as some confirmation of a prior determined or prior calculated result via some type of further determination or calculation, for example, directed to verification, or, possibly accuracy evaluation. Thus, confirming is at least a secondary procedure which is performed after a prior procedure with some type of evaluative or accuracy determinative aspect. Consideration of said page 57 reveals that it lacks any

Art Unit: 1631

disclosure of a "confirming" of a mass balance. Instead, said page 57 describes "(iii) Computation of a Temporal Concentration..." and "(iv) Calculation of Estimated Exposure Amount...". Said part (iii) sets forth a calculation of a residual amount. No confirming practice is set forth therein via any further determination or calculation. Said part (iv) sets forth an estimation wherein a concentration curve is integrated with the calculation of a mean concentration. Again there is no confirming of any parameter such as an verifying step or accuracy determining step. Further consideration of the instant specification reveals that page 56 describes a range of mass balance fluctuation such as exceeding, or, alternatively, within the range of  $\pm 5\%$ ; as being evaluated during a calculation procedure and is utilized for effecting an estimation nick time which is shorter for the range of fluctuation which exceeds the range of  $\pm 5\%$ . This more limited confirming practice reasonably has written basis, but this does not set forth "generic" confirming of mass balance as in the last three lines of claims 37, 42, and 43. The broad generic confirming limitation in claims 37, 42, 43, and therefore claims dependent therefrom is NEW MATTER.

### INFORMALITIES

The disclosure is objected to because of the following informalities:

In claim 37, line 1, the word "stimulating" appears to be misspelled as the corresponding word in line 2 is set forth as "simulation".

Consideration of the FAX, filed 5/27/03, has revealed that apparently one internal page did not transmit properly. The FAX has consecutive page numbering but the REMARKS pages has a page numbering gap for page 20. That is, the REMARKS

Art Unit: 1631

pages are numbered 18, 19, and 21 with what appear to be a missing page 20.

Applicants are requested to complete the record by supplying a complete copy of said REMARKS pages 18-21 with their next response.

Appropriate correction is required.

No claim is allowed.

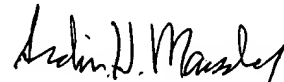
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 12, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER